



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE

United States Patent and Trademark Office

Address: COMMISSIONER FOR PATENTS

P.O. Box 1450

Alexandria, Virginia 22313-1450

www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/686,713	10/17/2003	Michelle M. Hanna	2072.0010006	9587
26111 7590 03/21/2008 STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C. 1100 NEW YORK AVENUE, N.W. WASHINGTON, DC 20005				
EXAMINER				
KIM, YOUNG J				
ART UNIT		PAPER NUMBER		
1637				
MAIL DATE		DELIVERY MODE		
03/21/2008		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/686,713

Applicant(s)

HANNA, MICHELLE M.

Examiner

Young J. Kim

Art Unit

1637

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 December 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 136, 137, 139-141, 143, 144 and 148-163 is/are pending in the application.
- 4a) Of the above claim(s) 150-163 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 136, 137, 139-141, 143, 144, 148 and 149 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

The present Office Action is responsive to the Amendment received on December 26, 2007.

Election/Restrictions

Newly submitted claims 150-163 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: the claims require an abortive transcript cassette, which comprises a structure that is not required in the claims as originally prosecuted, the structure of which is patentably distinct from.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 150-163 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Preliminary Remark

Claims 1-135, 138, 142, and 145-147 are canceled.

Claims 150-163 are new but withdrawn from further consideration as being drawn to a non-elected invention.

Claims 136, 137, 139-141, 143, 144, 148, and 149 are under prosecution herein.

Claim Rejections - 35 USC § 112

The rejection of claims 136, 137, and 139-149 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter, made in the Office Action mailed on July 26, 2007 is withdrawn in view of the Amendment received on December 26, 2007. The rejection pertaining to claim 142 is canceled in view of its cancellation.

Rejections, New Grounds – Necessitated by Amendment

Art Unit: 1637

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 137 and 141 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 137 is indefinite for reciting the phrase, “said abortive reiterative synthesis is abortive RNA transcription on a DNA template,” because the parent claim 136 has been amended to remove the phrase, “template.”

Claim 141 recites the limitation, “the template.”

There is insufficient antecedent basis for this limitation in the claim as the parent claim 136 has been amended to remove the term, “template.”

Claim Rejections - 35 USC § 102

The rejection of claims 136, 137, 140, and 145-149 under 35 U.S.C. 102(b) as being anticipated by Sasaki et al. (PNAS USA, March 1998, vol. 95, pages 3455-3460), made in the Office Action mailed on July 26, 2007 is withdrawn in view of the Amendment received on December 26, 2007.

Specifically, the method disclosed by Sasaki et al. do not employ a target site probe, wherein the target site probe and its target nucleic acid hybridize to form a bubble complex (see page 9, 2nd paragraph, Response).

The rejection of claims 136, 137, 139, 141-145, and 147-150 under 35 U.S.C. 102(b) as being anticipated by Daube et al. (PNAS USA, September 1994, vol. 91, pages 9539-9543) as evidenced by Daube (Biochemistry, 1994, vol. 33, pages 340-347, herein “Daube-2”), made in the Office Action mailed on July 26, 2007 is withdrawn in view of the Amendment received on December 26, 2007.

Specifically, the method disclosed by Daube-1 and Daube-2 do not employ a target site probe, wherein the target site probe and its target nucleic acid hybridize to form a bubble complex (see page 9, 2nd paragraph, Response).

Claim Rejections - 35 USC § 103 – New Rejection, Necessitated by Amendment

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 136, 137, 139, 140, 143, 144, 148, and 149 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dattagupta (U.S. Patent No. 5,215,899, issued June 1, 1993) in view of Sasaki et al. (PNAS USA, March 1998, pages 3455-3460).

Dattagupta discloses a method of detecting a target nucleic acid in a sample, wherein said method comprises:

- a) hybridizing a single-stranded target nucleic acid with a target site probe (see Figure 4);
- b) incubating said target nucleic acid and target site probe with an RNA polymerase (column 3, line 28), and an initiator (column 3, line 29; Figure 4, step (II));
- c) synthesizing an oligonucleotide transcript that is complementary to the initiation start site of the target-site probe:target nucleic acid duplex, wherein the initiator is extended, producing multiple reiterative oligonucleotide transcripts; and
- d) detecting the reiterative oligonucleotides (column 11, lines 26-35).

While Dattagupta do not explicitly disclose that the target-site probe and target nucleic acid hybridize to form a bubble complex, it is known and recognized in the art that when RNA

polymerase binds a nucleic acid duplex for transcription process, bubble complex is made on said duplex by the RNA polymerase. This fact is also implied in claim 143, wherein the claim recites that the transcription bubble forms in the “presence” of an RNA polymerase.

The initiator is disclosed as being labeled nucleotides (column 11, lines 50-55).

Dattagupta also disclose that the sample may comprise food, body fluid, urine, blood, milk, sputum, saliva, stool, lung aspirates, throat, or genital swabs, (column 7, lines 31-38), implicating that the target nucleic acid can be derived from any sources from which they are desired.

Dattagupta does not disclose the incorporation of a terminator in their reaction.

Sasaki et al. disclose a transcriptional sequencing method, said method comprising the steps:

a) hybridizing a single stranded target polynucleotide with a promoter construct comprising a sequence that hybridizes to the single-stranded target polynucleotide, and a region that can be detected by transcription by a polymerase (Figure 4, see primer comprising a sequence complementary to the target nucleic acid, and a region which is a T7 promoter or T3 promoter, which is recognized by a polymerase);

b) incubating said target polynucleotide with an RNA polymerase (with T7 or T3 RNA polymerase, see Figure 4), an initiator (or 1mM GMP; see page 3456, 2nd column, bottom paragraph) and a terminator (fluorescent dye terminator; see page 3457, 1st column, bottom paragraph);

c) synthesizing oligonucleotide transcripts that are complementary to the initiation start site of the promoter construct, until dye terminator is incorporated into the transcription product (see page 3457, Figure 4);

d) detecting the oligonucleotide transcripts by electrophoresis sequencing method (see Figure 5, page 3460, 1st column).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Dattagupta and Sasaki et al., thereby arriving at the invention as claimed for the following reasons.

Dattagupta clearly provides that multiple transcripts can be derived from their method, wherein the multiple transcripts are provided by the use of a nucleic acid promoter construct comprising a promoter sequence. While Sasaki et al. involve a different method for transcriptional sequencing, one of ordinary skill in the art would have clearly recognized that the method provided for by Dattagupta would have also capable of conducting transcriptional sequencing by incorporating nucleotide chain terminators in their reaction.

One of ordinary skill in the art would have had a reasonable expectation of success at combining the teachings since both methods involve the generation of nucleic acid constructs comprising promoter sequences.

Therefore, the invention as claimed is *prima facie* obvious over the cited references.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with

Art Unit: 1637

this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

The rejection of claims 136-147 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-34 of U.S. Patent No. 7,045,319, made in the Office Action mailed on July 26, 2007 is maintained for the reasons of record.¹

Applicants' request to hold the rejection in abeyance is noted (see page 9, 3rd paragraph, Response).

However, the instant application contains multiple substantive rejections over prior art and thus, rejection is maintained.

The Rejection:

Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the issued patents are narrower species of method which renders the broader claims of the instant application in a genus-species anticipatory way.

The provisional rejection of claims 136-147 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 26, 27, 103, 112, and 136-139 of copending Application No. 10/488,971 (herein, the '971 application), made in the Office Action mailed on July 26, 2007 is maintained for the reasons of record.

¹ Claims 148 and 149 are also rejected in all of the double patenting rejections, as they do not patentably distinguish the claimed subject matter from those which are made of record. Merely identifying the sources from which the target nucleic acids are derived from, when both (of the instant application and the conflicting patent/application) methods are drawn to a method of detecting target nucleic acids, the motivation to identify the target nucleic acid from variety of sources which are known, does not patentably distinguish the inventions.

Applicants' request to hold the rejection in abeyance is noted (see page 9, 3rd paragraph, Response).

However, the instant application contains multiple substantive rejections over prior art and thus, rejection is maintained.

The Rejection:

Although the conflicting claims are not identical, they are not patentably distinct from each other because claims of the '971 application are narrower species of method which renders the broader claims of the instant application in a genus-species anticipatory way.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

The provisional rejection of claims 136-147 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-22, 32-34, and 44 of copending Application No. 10/976,240 (herein, the '240 application), made in the Office Action mailed on July 26, 2007 is maintained for the reasons of record.

Applicants' request to hold the rejection in abeyance is noted (see page 9, 3rd paragraph, Response).

However, the instant application contains multiple substantive rejections over prior art and thus, rejection is maintained.

The Rejection:

Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the instant application and the claims of the '240 application require the

same method of reiteratively synthesizing oligonucleotide transcripts which are terminated, as well as employing an abortive promoter cassettes.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

The provisional rejection of claims 136-147 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 11-27 of copending Application No. 10/425,037, made in the Office Action mailed on July 26, 2007 is maintained for the reasons of record.

Applicants' request to hold the rejection in abeyance is noted (see page 9, 3rd paragraph, Response).

However, the instant application contains multiple substantive rejections over prior art and thus, rejection is maintained.

The Rejection:

Although the conflicting claims are not identical, they are not patentably distinct from each other because claims of the instant application and the claims of the '240 application require the same method of reiteratively synthesizing oligonucleotide transcripts which are terminated, as well as employing an abortive promoter cassettes.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

The provisional rejection of claims 136-147 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over pending (and/or elected) claims of copending

Application No. 10/602,045; 10/602,045; and 10/607,136, made in the Office Action mailed on July 26, 2007 is maintained for the reasons of record.

Applicants' request to hold the rejection in abeyance is noted (see page 9, 3rd paragraph, Response).

However, the instant application contains multiple substantive rejections over prior art and thus, rejection is maintained.

With regard to Applicants' request for clarification of Application no. 10/600,045, the citation contained a typographical error. The correct application no. should be 10/602,045.

The Rejection:

Although the conflicting claims are not identical, they are not patentably distinct from each other because as reasons already set forth above.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be

calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Inquiries

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Young J. Kim whose telephone number is (571) 272-0785. The Examiner is on flex-time schedule and can best be reached from 8:30 a.m. to 4:30 p.m (M-W and F). The Examiner can also be reached via e-mail to Young.Kim@uspto.gov. However, the office cannot guarantee security through the e-mail system nor should official papers be transmitted through this route.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Dr. Gary Benzion, can be reached at (571) 272-0782.

Papers related to this application may be submitted to Art Unit 1637 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 CFR 1.6(d)). NOTE: If applicant does submit a paper by FAX, the original copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED, so as to avoid the processing of duplicate papers in the Office. All official documents must be sent to the Official Tech Center Fax number: (571) 273-8300. For Unofficial documents, faxes can be sent directly to the Examiner at (571) 273-0785. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like

Art Unit: 1637

assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Young J. Kim/
Primary Examiner
Art Unit 1637
3/28/2008